

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA,

MEMORANDUM OPINION
15-CR-62

- against -

GERALD TIGHE and
STEPHEN KALINOSKI,

Defendants.

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GLASSER, Senior United States District Judge:

On July 14, 2017, defendants Gerald Tighe and Stephen Kalinoski each pled guilty to a one-count superseding information that charged them with conspiracy to commit wire fraud. ECF No. 88. At sentencing, on December 19, 2017, the Court gave each defendant the same non-custodial sentence: four years of probation (with special conditions, including six months of home confinement), property forfeiture, and a special assessment of \$100.00—a significant downward departure, for each defendant, from the ranges of imprisonment recommended by the Federal Sentencing Guidelines. ECF Nos. 115, 118. Although the defendants did not oppose restitution prior to sentencing or at their sentencing hearings, the Court reserved decision as to restitution at that time, and a hearing on restitution was scheduled for February 16, 2018. The stated purpose of the hearing was for the Court to better understand the basis for the specific amount of restitution being requested by Yale-New Haven Hospital (“YNHH”), one of the victims of the defendants’ fraud. Two weeks before the hearing, however, the defendants filed letters opposing in full the restitution requested by YNHH. ECF Nos. 127, 129. As indicated on the record at the February 16 hearing, and for the reasons outlined below, the Court will impose restitution in the full amount requested by YNHH.

BACKGROUND¹

Defendant Gerald Tighe was the founder, sole owner, and president of Med Prep Consulting, Inc. (“Med Prep”), a medical drug repackager located and incorporated in New Jersey. ECF No. 87 (“Superseding Information”) ¶¶ 1-2. Defendant Stephen Kalinoski was Med Prep’s director of pharmacy and its registered pharmacist in charge. *Id.* ¶ 3. As a medical drug repackager, Med Prep “manufactured, repackaged, processed, packed, labeled, held, compounded and distributed” drug products—products like “pain management medications, anesthesia and operating room drugs, and oncology and dialysis drugs.” *Id.* ¶ 1. Med Prep was thus subject to regulation by the United States Food and Drug Administration and the New Jersey Board of Pharmacy. *See id.* ¶¶ 4-5. Moreover, as a pharmacy licensed in New Jersey, Med Prep was bound by state law to comply with professional standards—including, most notably, Chapter 797 of the United States Pharmacopeia (“USP 797”), which sets forth professional standards for compounding drugs identified as sterile. *See id.* ¶¶ 14-16. The crux of the charge against the defendants—to which they pled guilty—is that (i) to gain market share, the defendants assured healthcare providers that Med Prep complied with USP 797 and that its drug products were safe for use by patients; (ii) in reality, Med Prep did **not** comply with USP 797 and basic sterility practices—saving itself money—and as a result Med Prep introduced adulterated and misbranded drugs into interstate commerce; and (iii) healthcare providers, in reliance on the defendants’ false and misleading representations regarding Med Prep’s compliance with USP 797, purchased drug products and services from Med Prep. *See id.* ¶¶ 38-41.

¹ The Court assumes the parties’ familiarity with the facts and procedural background of this case and reviews them only to the extent relevant to YNHH’s restitution claim.

One of the healthcare providers to which Med Prep sold drug products and services during the relevant time frame was YNHH. On March 13, 2013, YNHH “discovered that four [intravenous (“IV”)] bags of magnesium sulfate Med Prep sold to the hospital, which were labeled as sterile, had visible floating particles and were potentially contaminated.” *Id.* ¶ 59. Magnesium sulfate is a drug product “used to treat certain conditions in pregnant women, cardiac patients, and cancer patients, and is injected into the bloodstreams or muscles of such patients.” *Id.* ¶ 58. Subsequent investigation revealed that the four IV bags of magnesium sulfate from Med Prep *were* contaminated, with mold, and that, in fact, “Med Prep had sent the hospital at least four distinct shipments of magnesium sulfate drug product that were contaminated.” *Id.* ¶¶ 59-61. YNHH “determined that at least 21 patients received magnesium sulfate from the contaminated lot shipped by Med Prep.” *Id.* ¶ 61. YNHH treated those patients with anti-fungal antibiotics after the contamination was discovered. *Id.*

The superseding information set forth, in considerable detail, the unsanitary conditions and unsafe practices prevalent at Med Prep. Of particular relevance to the question of who or what caused the mold contamination in the magnesium sulfate sent to YNHH, the superseding information provided as follows:

- The defendants “conspired to introduce and introduced, or caused the introduction of, adulterated and misbranded drugs into interstate commerce.” *Id.* ¶ 38. “The adulterated drugs that the defendants [Tighe and Kalinoski] introduced or caused the introduction of into interstate commerce were adulterated because . . . the drugs consisted in whole or in part of a filthy, putrid and decomposed substance.” *Id.* ¶ 39.
- The defendants “did not inform healthcare providers of failures to comply with USP 797 and basic sterility practices, and breaches of aseptic technique in Med Prep’s cleanroom, which occurred repeatedly at Med Prep’s facility.” *Id.* ¶ 41.
- “Despite numerous inspections and warnings, Med Prep and the defendants [Tighe and Kalinoski] continued to handle sterile drugs in conditions below acceptable industry standards and standards with which [Tighe] and [Kalinoski] claimed that Med Prep complied.” *Id.* ¶ 48. For example:

- Several of the high-efficiency particulate air (“HEPA”) filters in Med Prep’s clean room repeatedly failed inspections, over a span of five years, but were neither fixed nor replaced. *Id.* ¶¶ 46, 49.
- “[A] cart was regularly pushed from Med Prep’s unsterile warehouse into the purportedly sterile cleanroom without first being sterilized.” *Id.* ¶ 50. Of the species of mold later found in the contaminated shipments of magnesium sulfate, one species “was the same species of mold found in Med Prep’s warehouse.” *Id.* ¶ 61.
- “[I]nstead of using sterile isopropyl alcohol to clean surfaces in the cleanroom in accordance with [USP 797], Med Prep continued to use non-sterile isopropyl alcohol. Among other deficiencies, non-sterile isopropyl alcohol is inadequate to kill mold spores.” *Id.* ¶ 51.
- “Although Med Prep received products with expiration dates assigned by the manufacturer, after it removed products from their original containers, it illegally assigned new, unsupported use by dates to the products.” *Id.* ¶ 52. One product to which Med Prep assigned unsupported use by dates was magnesium sulfate. *See id.* For magnesium sulfate, “Med Prep and KALINOSKI conducted a stability study but assigned use by dates that were much later than their own study purported to show. Med Prep failed to perform adequate sterility testing on [magnesium sulfate] . . . to support its beyond use dating.” *Id.*

In addition, the superseding information also asserted that the defendants’ misrepresentations induced healthcare providers, like YNHH, to purchase drug products from Med Prep. *See, e.g., id.* ¶ 41 (noting that healthcare providers purchased services from Med Prep “relying on [the defendants’] misrepresentations and omissions”); *id.* ¶ 55 (“The defendants [Tighe and Kalinoski] used these fraudulent use by dates to induce healthcare providers to use Med Prep’s services. . . . [T]he use of fraudulently extended use by dates gave Med Prep an advantage over competitors and caused healthcare providers to choose Med Prep’s services.”); *see also id.* ¶ 25 (“By virtue of the requirements set forth in USP 797, and TIGHE’s and KALINOSKI’s assurances that Med Prep was in compliance with such requirements, patients and healthcare providers had an expectation that the drugs they received would be sterile and stable.”).

On July 14, 2017, Tighe and Kalinoski each pled guilty to the superseding information. ECF No. 88. Before accepting the defendants’ pleas, the Court satisfied itself that the defendants

understood what they were pleading guilty to and that there was a factual basis for their guilty pleas. Among other things, the Court made sure the defendants knew that the section in the superseding information containing the charge, conspiracy to commit wire fraud, explicitly incorporated all of the preceding paragraphs in the information (i.e., all of the paragraphs cited above in this opinion). Tr. of Criminal Cause for Pleading at 9:19-10:11 (July 14, 2017). The Court asked the defendants whether they had read all of that information and discussed it with their lawyers, and they responded that they had. *Id.* at 10:5-11.

All of the above-cited allegations from the superseding information were reproduced—nearly verbatim, and certainly in substantively identical language—in the defendants’ respective presentence reports (“PSRs”). *See* ECF No. 93 (“Kalinowski PSR”); ECF No. 94 (“Tighe PSR”). But unlike the superseding information, the defendants’ PSRs also discussed restitution. Specifically, the defendants’ initial PSRs asserted that the Mandatory Victim Restitution Act of 1996 applied to the defendants’ offense and that, pursuant to that law, “restitution shall be ordered in this case.” Kalinowski PSR ¶¶ 47, 112; Tighe PSR ¶¶ 48, 112. The initial PSRs also identified the victims of the defendants’ offense as “the approximately 200 healthcare providers to whom Med Prep sold drugs”; seven of those healthcare providers, including YNHH, were identified by name. Kalinowski PSR ¶¶ 47, 112; Tighe PSR ¶¶ 48, 112. The initial PSRs indicated that the government could not yet provide a breakdown of the losses for the victim healthcare providers, since they had not yet submitted affidavits of loss. Kalinowski PSR ¶¶ 47, 112; Tighe PSR ¶¶ 48, 112. After YNHH later submitted affidavits of loss, however, the government filed a second addendum to each defendant’s PSR in which it detailed YNHH’s declared losses.² ECF No. 103

² The first addendum to each defendant’s PSR made minor, unrelated amendments to the initial PSR. *See* ECF Nos. 98-99. Kalinowski’s PSR also included a third addendum, which revised the PSR to reflect Kalinowski’s updated employment status. *See* ECF No. 111.

(“Kalinowski Second Add.”); ECF No. 105 (“Tighe Second Add.”). The addendum explained that YNHH’s losses were “in relation to the Med Prep drug contamination arising from contaminated drug products Med Prep provided to Yale-New Haven Hospital in 2013,” and it included the following table:

Activity	Expense
Legal fees and costs associated with the collection, review and preservation of documents provided to the Department of Justice over six rolling document productions (52,601 pages provided).	\$63,194.15
Patient and physician notification concerning contaminated drug product from Med Prep.	\$80,038.00
Drug cost for returned drug product to Med Prep, terminated consigned drug product with Med Prep, and purchased antifungal prophylactic medication.	\$386,777.00
Patient disease surveillance for patients potentially exposed to contaminated drug product from Med Prep.	\$26,434.00
Administrative time responding to the Med Prep contamination (legal, regulatory, financial and administrative: 1,451 hours spent).	\$263,857.00
Pharmacy in-house admixture services; additional staffing dedicated to providing replacement drug products in connection with Med Prep contamination (over-time, new staff, and related hours).	\$485,845.00
Pharmacy response (sequester inventory, and formulary of contaminated drug products from Med Prep).	\$59,202.00
Total:	1,365,347.15

Kalinowski Second Add. at 1-2; Tighe Second Add. at 1-2. The addendum also stated that, according to YNHH’s affidavits of loss, the hospital had saved \$481,000 in service fees by terminating its contract with Med Prep. Kalinowski Second Add. at 2; Tighe Second Add. at 2.

The government filed Kalinoski's and Tighe's PSRs on September 13, 2017 and September 28, 2017, respectively. *See* ECF Nos. 93-94. The second addendum to Kalinoski's PSR was filed on November 27, 2017, and the second addendum to Tighe's PSR was filed on December 1, 2017. *See* ECF Nos. 103, 105. At no point prior to their sentencing hearings, on December 19, 2017, did either defendant ever object to any portion of his presentence report or its addenda, with one minor exception: Tighe provided an "objection/clarification" to the "Financial Condition: Ability to Pay" section of his initial PSR, which the government then revised accordingly in its first addendum to his PSR. *See* ECF 98 at 1. At the sentencing hearings, the defendants' counsel explicitly stated that they had no objections to the PSRs (as revised by their addenda), and the Court therefore adopted the PSRs in full. *See* Tighe Sentencing Tr. at 2:12-19; Kalinoski Sentencing Tr. at 2:14-19. The Court proceeded to sentence each defendant to four years of probation (with special conditions, including six months of home confinement). *See* ECF Nos. 115, 118. The Court also assessed a \$100.00 fine to each defendant and entered orders of property forfeiture, which property forfeitures the defendants had consented to in their plea agreements. *See* ECF Nos. 115, 118.

As to restitution, the Court reserved decision on that issue, as to both defendants, at the December 19 hearings. Neither defendant had objected to restitution—neither in principle nor to YNHH's claim in particular; as expressed during Tighe's sentencing hearing, the Court understood restitution to be uncontested.³ *See* Tighe Sentencing Tr. at 14:19-24. Nonetheless, as the Court explained at the time, it had some questions regarding the basis for the specific amount of restitution being requested by YNHH—in particular, regarding the expenses described, in the second addendum to each defendant's PSR, as "[a]dministrative time responding to Med Prep

³ Counsel for Kalinoski even argued, in his sentencing memorandum, that one reason Kalinoski should be given a lenient, non-custodial sentence was that "restitution will be devastating to him." ECF No. 102 at 2.

contamination.” Kalinoski Second Add. at 1; Tighe Second Add. at 1; *see also* Tighe Sentencing Tr. at 32:20-33:8 (discussing that topic); Kalinoski Sentencing Tr. at 26:16-19 (indicating that restitution for Kalinoski would be dealt with “in the same way” as for Tighe). Therefore, the Court requested that YNHH provide documentation showing how it calculated those expenses, Tighe Sentencing Tr. at 35:22-25, and a hearing on restitution was scheduled for February 16, 2018, *id.* at 36:25-37:1; Kalinoski Sentencing Tr. at 26:16-19.

Approximately two weeks before that scheduled hearing, on February 3, 2018, Tighe filed a letter with the Court opposing YNHH’s restitution claim, in full. ECF No. 127. Kalinoski joined in that letter three days later. ECF No. 129. Tighe’s letter opposing YNHH’s restitution claim does not quibble with YNHH’s calculations or otherwise dispute the *amount* of restitution that YNHH is requesting. Instead, it attacks the very premise of YNHH’s restitution claim—the claim that Med Prep is responsible for the contaminated magnesium sulfate discovered at YNHH in March of 2013. *See* ECF No. 127 at 3. Tighe argues that Med Prep was not the source of the mold—or, at least, that the government has not proved that it was—and that, therefore, the defendants did not directly and proximately cause any of the financial losses YNHH incurred as a result of the contamination. *See id.* at 3-7.

The government filed a response to Tighe’s letter on February 13, 2018, asking that the Court grant YNHH’s restitution claim in its entirety. ECF No. 130. The government submitted with its letter, among other exhibits, affidavits from YNHH with specific documentation regarding its declared losses. *See id.*, Exs. 13-14. As indicated in the government’s letter and in the supporting affidavits from YNHH, YNHH is seeking \$825,363.15 in restitution. *See id.*, Exs. 13-14; ECF No. 132 at 12. This number comprises the expenses listed in the second addendum to

each defendant's PSR (detailed above), less the money YNHH saved by canceling the remainder of its contract with Med Prep.⁴

The hearing on restitution took place as scheduled, on February 16, 2018. ECF No. 133.

DISCUSSION

I. The Mandatory Victim Restitution Act

The Mandatory Victim Restitution Act of 1996 (the "MVRA") provides that, in all sentencing proceedings for convictions of "an offense against property under [title 18], including any offense committed by fraud or deceit," a court "*shall* order . . . that the defendant make restitution to the victim of the offense." 18 U.S.C. § 3663A(a)(1), (c)(1)(A)(ii) (emphasis added). Under the MVRA, a "victim" is "a person directly and proximately harmed as a result of the commission of an offense for which restitution may be ordered." *Id.* § 3663A(a)(2). "[T]he purpose of restitution is essentially compensatory: to restore a victim, to the extent money can do so, to the position he occupied before sustaining injury." *United States v. Boccagna*, 450 F.3d 107, 115 (2d Cir. 2006) (citing *Hughey v. United States*, 495 U.S. 411, 416 (1990)).

The MVRA places two limits on a court's authority to order restitution under its terms. First, the statute enumerates four categories of damages. *Id.* § 3663A(b)(1)-(4). In a case where the victims have not suffered bodily injury or death, only two of those categories are recoverable: (i) "damage to or loss or destruction of property" and (ii) "necessary . . . expenses incurred during participation in the investigation or prosecution of the offense or attendance at proceedings related to the offense." *Id.* § 3663A(b)(1), (4). This second category, "necessary" expenses, lacks clear

⁴ The amount now requested for "[a]dministrative time responding to Med Prep contamination" expenses is \$58,984 lower than the amount of those expenses listed in the second addenda to the defendants' PSRs, but otherwise the expense amounts detailed in the submitted affidavits are the same as in the second addenda. *Compare* Kalinoski Second Add., *and* Tighe Second Add., *with* ECF No. 130, Exs. 13-14.

definition—necessity is sometimes in the eye of the bill-holder—but as a general matter, the Second Circuit “takes a broad view of what expenses are ‘necessary.’” *United States v. Maynard*, 743 F.3d 374, 381 (2d Cir. 2014). In *United States v. Amato*, for example, the Second Circuit held that “‘necessary’ expenses, under § 3663A(b)(4), ‘may include attorney fees and accounting costs.’” 540 F.3d 153, 159 (2d Cir. 2008). More specifically, in *Amato*, the court affirmed an order of restitution “for attorney’s fees and accounting fees incurred by an internal investigation that uncovered fraud—notwithstanding that not all of the effort and expense was requested by the government.” *Maynard*, 743 F.3d at 381 (citing *Amato*, 540 F.3d at 159-60, 162)). Similarly, in *United States v. Bahel*, the Second Circuit “affirmed restitution for legal fees incurred when the United Nations hired outside counsel to conduct an internal investigation rather than use on-staff lawyers.” *Maynard*, 743 F.3d at 381 (citing *United States v. Bahel*, 662 F.3d 610, 647-48 (2d Cir. 2011)).

The second limitation on a court’s authority to order restitution under the MVRA follows from the statute’s definition of victim: “[T]he MVRA makes restitution available only for those losses that were directly and proximately caused by the offenses of conviction.” *United States v. Hatfield*, No. 06-CR-550, 2015 WL 13385926, at *4 (E.D.N.Y. Mar. 27, 2015) (citing *United States v. Silkowski*, 32 F.3d 682, 689 (2d Cir. 1994)). This limitation “encompasses the traditional ‘but for’ and proximate cause analyses.” *In re Rendon Galvis*, 564 F.3d 170, 175 (2d Cir. 2009). And “proximate cause, in turn, is ‘a flexible concept grounded in policy considerations.’” *Hatfield*, 2015 WL 13385926, at *4 (quoting *United States v. Gamble*, 709 F.3d 541, 556 (6th Cir. 2013)); see also, e.g., *Holmes v. Sec. Investor Protection Corp.*, 503 U.S. 258, 268 (1992) (“At bottom, the notion of proximate cause reflects ‘ideas of what justice demands, or of what is administratively possible and convenient.’” (quoting W. Keeton, D. Dobbs, R. Keeton, & D. Owen, *Prosser and*

Keeton on Law of Torts § 41, at 264 (5th ed. 1984))); *Nat'l Asbestos Workers Med. Fund v. Philip Morris, Inc.*, 74 F. Supp. 2d 221, 225 (E.D.N.Y. 1999) (“Proximate cause analysis is driven by considerations of policy, fairness, and practicability.”). As one court has noted, the causation requirement is broader—i.e., the scope of potentially recoverable damages is wider—“[i]n cases where a defendant is found guilty for his role in a scheme or conspiracy.” *Hatfield*, 2015 WL 13385926, at *4. The statute specifically provides that, in such cases, the definition of victim includes those “harmed by the defendant’s criminal conduct in the course of the scheme, conspiracy, or pattern [of criminal activity].” 18 U.S.C. § 3663A(a)(2). “The effect of this language is to make a conspiring defendant liable in restitution for the full amount of loss to the victims, including the loss attributable to uncharged or unconvicted counts.” *Hatfield*, 2015 WL 13385926, at *4.

In cases where restitution is disputed, “[a]ny dispute as to the proper amount or type of restitution shall be resolved by the court by the preponderance of the evidence.” 18 U.S.C. § 3664(e). In such cases, the government bears “[t]he burden of demonstrating the amount of the loss sustained by a victim as a result of the offense.” *Id.*; see also *United States v. Smathers*, 879 F.3d 453, 460 (2d Cir. 2018) (describing burdens of proof under the MVRA).

II. YNHH’s Restitution Claim

Tighe and Kalinoski pled guilty to conspiracy to commit wire fraud, 18 U.S.C. § 371. Since conspiracy to commit wire fraud is an “offense committed by fraud,” the MVRA applies, and restitution is thus mandatory for losses directly and proximately caused by the offense. See *id.* § 3663A(a)(1), (c)(1)(A)(ii). The defendants do not dispute this much. But the defendants have objected to the only restitution claim submitted, by YNHH, arguing that their offense conduct did not directly and proximately cause YNHH’s losses. Below, the Court considers this objection,

reviews whether the categories of losses declared by YNHH are recoverable under the MVRA, and addresses whether YNHH has submitted sufficient documentation to support its declared losses.

A. The Defendants' Offense Conduct Directly and Proximately Caused the Contamination at YNHH and YNHH's Resulting Financial Losses

Regarding whether the defendants directly and proximately caused the contamination at YNHH and YNHH's resulting financial losses, the Court can and does dispose of this issue solely on the basis of the defendants' failure to timely object to their PSRs. The defendants' PSRs, as amended by their addenda, clearly placed blame for the contamination and YNHH's resulting losses on Med Prep and the defendants. Rule 32 of the Federal Rules of Criminal Procedure is dispositive here. Rule 32(f)(1) provides that "[w]ithin 14 days after receiving the presentence report, the parties must state in writing any objections, including objections to material information, sentencing guideline ranges, and policy statements contained in or omitted from the report." Fed. R. Crim. P. 32(f)(1). And under Rule 32(i)(3)(A), "[a]t sentencing, the court . . . may accept any undisputed portion of the presentence report as a finding of fact." Fed. R. Crim. P. 32(i)(3)(A). Taken together, these two provisions of Rule 32 mean that, if a defendant fails to timely object to a fact in his PSR, the court may adopt that fact for purposes of sentencing. The defendants here did not object to the portions of their PSRs blaming them for the contamination and YNHH's resulting losses until long after the time to do so had passed.

A court may, "for good cause," ignore the time limitation of Rule 32(f)(1). *See* Fed. R. Crim. P. 32(b)(2) ("The court may, *for good cause*, change any time limits prescribed in this rule." (emphasis added)); *id.* 32(i)(1)(D) ("At sentencing, the court . . . may, *for good cause*, allow a party to make a new objection at any time before sentence is imposed." (emphasis added)). But while a court *may* consider an untimely objection to a PSR, it need not do so. In *United States v.*

Wernick, for example, a court denied a defendant's post-sentencing motion to strike from the PSR any statements suggesting he had sexually abused children, upon concluding that Rule 32 "did not empower [the court] to amend portions of the PSR after sentencing." 673 F. App'x 21, 24 (2d Cir. 2016). The Second Circuit affirmed, reasoning that because the defendant had failed to timely object to the PSR—indeed, at sentencing his counsel had affirmatively stated that he had no objections to it—the district court was entitled to rely on the PSR's findings. *See id.* at 24-25.

Wernick involved a post-sentencing objection, but courts have also refused to consider untimely objections to a PSR before sentencing. Consider *United States v. Lindsey*, 827 F.3d 733 (8th Cir.), *cert. denied*, 137 S. Ct. 413 (2016). There, the defendant failed to timely object to the inclusion in his PSR of prior state convictions, but he did file an untimely objection, forty-four days after receipt of the preliminary PSR, and objected again at the sentencing itself. *See id.* at 735-36. The government failed to present any additional evidence of those prior state convictions, but the court still adopted the defendant's prior criminal history as set forth in the PSR; doing so allowed the court to use those convictions as predicate offenses under the Armed Career Criminal Act, which predicate offenses subjected the defendant to a mandatory-minimum sentence. *See id.* at 734, 736. On appeal, the defendant argued that the district court had erred in adopting his criminal history over his objections. *Id.* at 736. The Eighth Circuit rejected this argument and affirmed the district court's sentencing decision, holding that the defendant's failure to timely object to the criminal history in his PSR allowed the court to adopt it as fact:

In the absence of a clearly stated, timely objection to the fact or existence of his prior convictions, the district court did not clearly err in recognizing the three second-degree assault convictions listed in the PSR. Although it is true that a PSR "is not evidence and is not a legally sufficient basis for making findings on contested issues of material fact," *United States v. Richey*, 758 F.3d 999, 1002 (8th Cir. 2014) (internal quotation omitted), it is also well established that "a district court may regard as true facts contained in the presentence report to which no specific objection is made." *United States v. May*, 413 F.3d 841, 849 (8th Cir.

2005) (citations omitted). In fact, the district court “may accept any undisputed portion of the presentence report as a finding of fact” pursuant to Federal Rule of Criminal Procedure 32(i)(3)(A). We have explicitly held that *the conjunction of Federal Rules 32(f)(1) and 32(i)(3)(A) “establish that an untimely objection to a fact in the presentence report does not change the fact’s ‘undisputed’ status, and the district court may adopt the fact without requiring any additional evidence.”* *May*, 413 F.3d at 849. *Because any objection made in Defendant’s Position Regarding Sentencing memorandum or at the sentencing hearing was untimely, the existence of Lindsey’s convictions remained undisputed facts which the district court properly adopted.*

Id. at 738 (emphasis added).

Here, the defendants’ PSRs (as amended by their addenda) made clear that the defendants were responsible for—i.e., that their offenses directly and proximately caused—the contamination at YNHH and the financial losses that YNHH incurred as a result of that contamination. First, each defendant’s PSR (i) indicated that “restitution shall be ordered in this case”; (ii) stated that “[t]he victims of the offense of conviction were the approximately 200 health care providers to whom Med Prep sold drugs”; and (iii) identified seven of those healthcare providers, including YNHH. Kalinoski PSR ¶¶ 47, 112; Tighe PSR ¶¶ 48, 112. Second, the PSRs stated that the defendants “introduced, or caused the introduction of, adulterated . . . drugs into interstate commerce,” drugs that were adulterated because they “consisted in whole or in part of a filthy, putrid and decomposed substance.” Kalinoski PSR ¶¶ 18-19; Tighe PSR ¶¶ 19-20. Third, the PSRs asserted that, “between February 1, 2013 and March 1, 2013, Med Prep had sent YNHH at least four distinct shipments of magnesium sulfate drug product that were contaminated.” Kalinoski PSR ¶37; Tighe PSR ¶ 38; *see also* Kalinoski PSR ¶ 49 (“[Defendants] provided medications to healthcare providers which were . . . contaminated with mold[.]”); Tighe PSR ¶ 50 (same). Fourth, the PSRs enumerated the many unsanitary conditions and unsafe practices at Med Prep—conditions and practices that, contrary to the defendants’

representations to healthcare providers about their business, were out of compliance with USP 797, and one or more of which likely led to the contamination at YNHH. *See, e.g.*, Kalinoski PSR ¶¶ 22, 25 (highlighting HEPA filters’ repeated inspection failures); *id.* ¶ 25 (noting continued use of non-sterile isopropyl alcohol, which is inadequate to kill mold spores); *id.* ¶¶ 25, 38 (noting that “a cart was regularly pushed from Med Prep’s unsterile warehouse into the purportedly sterile cleanroom without first being sterilized” and that “[o]ne of the species of mold found in the contaminated magnesium sulfate [at YNHH] was the same species of mold found in Med Prep’s warehouse”); Tighe PSR ¶¶ 23, 26, 39 (same). Fifth, the PSRs stated that healthcare providers—including YNHH—purchased drugs from Med Prep in reliance on the defendants’ false representations of compliance with USP 797 and standard sterility practices. Kalinoski PSR ¶ 20; Tighe PSR ¶ 21. Finally, the second addendum to each defendant’s PSR disclosed YNHH’s declared losses, based on affidavits of loss from YNHH; those declared losses, broken down by category, made abundantly clear that the government and YNHH held the defendants responsible for the contamination at YNHH and the resulting pecuniary losses incurred by YNHH. *See* ECF Nos. 103, 105.

Faced with PSRs that clearly blamed them and Med Prep for the contamination at YNHH and YNHH’s resulting financial losses, the defendants did not object—at least, not until well after Rule 32’s fourteen-day window for objections had closed. Each defendant received his PSR and its second addendum in September 2017 and December 2017, respectively. Yet aside from Tighe’s minor clarification regarding his financial condition, neither defendant objected to anything in his PSR prior to Tighe’s February 2018 letter to the Court—quite the contrary. At sentencing, the defendants’ counsel stated that they had

reviewed the PSRs and had no objections to them. *See* Tighe Sentencing Tr. at 2:12-17; Kalinoski Sentencing Tr. at 2:14-17. Therefore, as to each defendant, the Court announced that it was adopting the PSR in its entirety. *See* Tighe Sentencing Tr. at 2:18-19; Kalinoski Sentencing Tr. at 2:18-19. At this point, the defendants' opportunity to object to their PSRs had passed.

Seeking to avoid the consequences of their silence, the defendants now argue that they did not receive the second addendum to the PSR, detailing YNHH's restitution claim, until the day before their sentencing hearing and that, therefore, they "did not have a full and fair opportunity to carefully review and consider this claim." ECF No. 127 at 1 n.1. Even taking this claim at face value, Tighe did not file his letter opposing restitution until February 3, 2018, which was a month and a half after he claims to have received the second addendum—well beyond Rule 32's fourteen-day window for objections. In any event, the defendants' counterfactual complaint rings hollow. To begin with, if the defendants truly felt that they had not had sufficient time to review the addenda to their PSRs, then they could and should have said so at sentencing (or, better yet, requested a continuance); they did not.⁵ More importantly, the record belies the notion that the defendants did not learn of YNHH's restitution claim until they received the second addendum to their PSRs. The defendants were put on notice of YNHH's restitution claim and its basis as early as June 30, 2017. On that date, the government informed the defendants that it anticipated YNHH would make a claim for restitution and directed the defendants to an article describing the hospital's response to the mold contamination. *See* ECF No. 130, Exs. 1-2. The

⁵ Kalinoski's counsel even specifically stated that he had reviewed the addenda to the PSR with his client and that they had no objections. Kalinoski Sentencing Tr. at 2:14-17.

government even explained that the article set forth “a summary of YNHH’s losses . . . and methodology for calculating the same,” *id.*, Ex. 1, at 1-2; YNHH’s restitution claim ultimately did largely reflect its losses as described in that article, *see id.*, Ex. 2. Moreover, as detailed above, the initial PSRs themselves signaled clearly that (i) YNHH was a victim of the defendants’ offense conduct and (ii) Med Prep and the defendants caused the contamination at YNHH. Lastly, the government’s sentencing memorandum for each defendant—filed publicly on ECF two weeks before the sentencing hearings—included a section discussing YNHH’s restitution claim. *See* ECF No. 106 at 4; ECF 107 at 4.

In short, for all of the above reasons, the Court does not accept the defendants’ post-hoc justification for their failure to object to the restitution claim in their PSRs. In all likelihood, their silence on this score was strategic: Prior to their initial sentencing hearings, the defendants’ primary aim was likely to avoid custodial prison sentences, and vigorous objections to restitution may well have undercut their studied poses of remorse and acceptance of responsibility.⁶ Whatever the reason, the defendants did not timely object to their PSRs, and the Court does not see good cause to consider their belated objection now. Accordingly, the Court reaffirms its adoption of the PSRs and accepts as fact, under Rule 32, that the defendants’ offense conduct directly and proximately caused the contamination at YNHH and YNHH’s resulting financial losses.

⁶ As indicated in their PSRs, each defendant received an offense level reduction, under the Federal Sentencing Guidelines, for acceptance of responsibility. Kalinoski PSR ¶ 66; Tighe PSR ¶ 66. At the restitution hearing, on February 16, 2018, the representative from the probation department said that if the defendants had, prior to sentencing, made the arguments they are making now, the probation department would have reconsidered whether to recommend that the defendants receive that offense level reduction.

B. All of the Damages Requested by YNHH Are Recoverable Under the MVRA

Having concluded that the defendants' offense conduct directly and proximately caused the contamination at YNHH and the hospital's resulting losses, the question remains whether those losses fall into the categories of damages recoverable under the MVRA. Where, as here, the victim has not suffered bodily injury or death, the only categories of damages recoverable are (i) "damage to or loss or destruction of property" and (ii) "necessary . . . expenses incurred during participation in the investigation or prosecution of the offense or attendance at proceedings related to the offense." 18 U.S.C. § 3663A(b)(1), (4). The defendants have not actually argued that YNHH's declared losses do not fall into these categories. Even if they had, however, such an argument would have been unavailing. As discussed below, all of the damages requested by YNHH are recoverable under the MVRA.

1. YNHH's losses due to (i) returning recalled drug products to Med Prep and (ii) terminating consigned drug products housed at Med Prep are recoverable as loss of property

The most straightforward losses declared by YNHH are those due to (i) returning the drug products that Med Prep recalled after the contamination was discovered at Med Prep and (ii) terminating all consigned medication housed at Med Prep. *See* Kalinski Second Add. at 1; Tighe Second Add. at 1; ECF No. 130, Ex. 13, at 2. Med Prep never credited or reimbursed YNHH for the returned and terminated drug products; YNHH simply absorbed the loss. ECF No. 130, Ex. 13, at 2. This loss qualifies as loss of property and, as such, is recoverable under the MVRA. *See* 18 U.S.C. § 3663A(b)(1). Where, as here, return of the lost property "is impossible, impracticable, or inadequate," a restitution order shall require the defendant to "pay an amount equal to—(i) the greater of—(I) the value of the property on the date of the damage, loss, or destruction; or (II) the value of the property on the date of the sentencing." *Id.* § 3663A(b)(1)(B). The Court accepts

YNHH's undisputed assertions as to the value of the recalled drug products and the consigned drug products that were terminated.

2. *YNHH's legal fees and costs are recoverable as "necessary . . . expenses incurred during participation in the investigation or prosecution of the offense or attendance at proceedings related to the offense"*

YNHH has also requested restitution for the "[l]egal fees and costs associated with the collection, review and preservation of documents provided to the Department of Justice over six rolling document productions." Kalinsoki Second Add. at 1; Tighe Second Add. at 1; ECF No. 130, Ex. 14, at 2. As discussed above, the Second Circuit has held that "necessary" expenses, under § 3663A(b)(4), "may include attorney fees and accounting costs." *Amato*, 540 F.3d at 159. In so holding, the court identified three elements that must be present for such costs and fees to be included in a restitution order: The expenses must be (1) "necessary," (2) "incurred during participation in the investigation or prosecution of the offense or attendance at proceedings related to the offense," and (3) incurred by a "victim" within the meaning of the MVRA (i.e., "a person directly and proximately harmed as a result of the commission of an offense for which restitution may be ordered," 18 U.S.C. § 3663A(a)(2)). *Amato*, 540 F.3d at 160. In *Bahel*, the court found that these elements were satisfied—and affirmed an order of restitution—as to legal fees incurred by outside counsel rather than on-staff lawyers. *See Bahel*, 662 F.3d at 647-48.

Here, the legal fees and costs for which YNHH requests restitution all relate to YNHH's responses to various subpoenas issued to it by the Department of Justice in connection with this case. *See* Kalinsoki Second Add. at 1; Tighe Second Add. at 1; ECF No. 130, Ex. 14, at 1-2. The Court finds that these legal fees and costs meet the three requirements for inclusion in a restitution order, under the MVRA, as "necessary" expenses: YNHH is a victim within the meaning of the MVRA, and the legal fees and costs for which it requests restitution were (i) necessary and (ii)

incurred during its participation in the investigation and prosecution of the defendants' conspiracy to commit wire fraud. Accordingly, these legal fees and costs are recoverable under the MVRA.

3. *The remaining losses for which YNHH requests restitution are also recoverable as “necessary . . . expenses incurred during participation in the investigation or prosecution of the offense or attendance at proceedings related to the offense”*

All of the remaining expenses declared as losses by YNHH are recoverable as “necessary” expenses under § 3663A(b)(4). To review, those expenses are for the following activities, all of which YNHH undertook in response to its discovery of the contaminated drug products from Med Prep:

- patient and physician notification concerning contaminated drug products;
- the purchase of anti-fungal prophylactic medication, which was subsequently used to treat the patients who had received the contaminated drug products;
- patient disease surveillance for patients potentially exposed to contaminated drug product;
- administrative time responding to the contamination (legal, regulatory, finance, administration)—e.g., hospital staff's participation in the various regulatory responses to the contamination;
- pharmacy in-house admixture services and additional staffing dedicated to providing replacement drug products in connection with the contamination (overtime, new staff, and related hours); and
- pharmacy response to the contamination (sequester, inventory, and formulary of contaminated drug products).

See Kalinski Second Add. at 1-2; Tighe Second Add. at 1-2; ECF No. 130, Ex. 13, at 2-4.

Although no court appears to have dealt with restitution requests of precisely this type, the Second Circuit's treatment of “necessary” expenses under § 3663A(b)(4) is instructive. As a general matter, and as noted above, the Second Circuit has said it “takes a broad view of what expenses are ‘necessary.’” *Maynard*, 743 F.3d at 381. This broad view was on display in *Amato* and *Bahel*, where the court affirmed restitution orders for attorney's fees. In *Amato*, the court

affirmed such an order even though much of the effort and expense had not been requested by the government, *see Amato*, 540 F.3d at 159-60, 162, and in *Bahel*, the court affirmed the order even though the victim had expended legal fees on outside counsel instead of its own staff lawyers, *Bahel*, 662 F.3d at 647-48. In *Amato*, moreover, the court cited favorably to *United States v. Phillips*, 477 F.3d 215 (5th Cir. 2007), a case where the Fifth Circuit faced a restitution claim quite similar to YNHH's. *See Amato*, 540 F.3d at 159-60. In *Phillips*, the defendant had been convicted of violating the Computer Fraud and Abuse Act by hacking into a university's computer system and stealing Social Security numbers and other confidential information. *See Phillips*, 477 F.3d at 217. The Fifth Circuit affirmed the district court's award of restitution, under § 3663A(b)(4) of the MVRA, for the costs that the victim university incurred in (i) conducting computer damage and systems evaluation and (ii) contacting individuals whose information had been stolen as a result of the defendant's computer hacking. *See id.* at 224-25.

More recently, in *United States v. Maynard*, the Second Circuit held that a bank that had been robbed should not receive restitution to reimburse it for the cost of producing wanted posters and hiring extra security. *See* 743 F.3d 374, 380-82 (2d Cir. 2014). There, the court concluded that those expenses "were not necessary to the investigation or prosecution of the offense" and so were not recoverable under § 3663A(b)(4). *See id.* at 382. But part of the court's reasoning was that "the bank had no interest to protect by an independent investigatory effort—and certainly had no duty to undertake it." *Id.* at 381. The court expressly contrasted the circumstances of the bank in *Maynard* with those of the victims in *Amato* and *Bahel*; in *Amato* and *Bahel*, the victims' internal investigations—which pre-dated the government's investigation and prosecution and unmasked the fraud—were "necessary because the entity had interests to protect (the integrity of its ongoing operations and reputation, at the least) as well as a duty to protect those interests." *Id.* at 381.

Maynard thus suggests that “where the defendants have jeopardized some ongoing, legitimate interest of the victim, expenses incurred to protect that interest will be deemed necessary.” *Hatfield*, 2015 WL 13385926, at *4 (citing *Maynard*, 743 F.3d at 381).

Applying these precedents, the Court concludes that all of the remaining expenses for which YNHH seeks restitution were “necessary . . . expenses incurred during participation in the investigation or prosecution of the offense or attendance at proceedings related to the offense,” 18 U.S.C. § 3663A(b)(4), and thus recoverable under the MVRA. The Court finds many of these expenses to be analogous to those awarded by the Fifth Circuit in *Phillips*: Just as the victim university in *Phillips* needed to conduct computer damage and systems evaluation and contact individuals whose information had been stolen as a result of defendant’s computer hacking, YNHH here needed to (i) sequester and inventory the contaminated drug products from Med Prep, (ii) examine the sequestered drug products for mold, and (iii) notify patients potentially affected by the contamination. The Court also finds that YNHH incurred these remaining expenses to protect an “ongoing, legitimate interest.” *Hatfield*, 2015 WL 13385926, at *4. Specifically, YNHH has an ongoing, legitimate interest in the health of its patients, and it has a duty to protect that interest—a duty that compelled the hospital to act as it did. Most obviously, the hospital needed to purchase anti-fungal medication with which to treat the patients who had received the contaminated drug products, and it similarly had an obligation to monitor patients potentially exposed to contaminated drug products. YNHH’s interest in its patients’ health also demanded that it participate in the various regulatory responses to the contamination, responses designed to get to the bottom of the contamination and to prevent a similar occurrence in the future. Finally, the hospital also clearly needed to replace the drugs that had been contaminated. In sum, all of the steps that YNHH took

were reasonably necessary under the circumstances in order for the hospital to protect its legitimate interest in the health of its patients.

C. YNHH Has Provided Sufficient Documentation of Its Losses

We turn now, finally, to the subject for which the Court initially requested a hearing on restitution: YNHH's documentation of its expenses, in particular the expenses categorized as "[a]dministrative time responding to the Med Prep contamination" in the second addendum to each defendant's PSR. Tighe Second Add. at 1; Kalinoski Second Add. at 1. In response to the Court's request for specific documentation regarding YNHH's contamination-related expenses, the government submitted, along with its memorandum, two affidavits from YNHH: one from Lorraine Lee, Vice President and Chief Pharmacy Officer at YNHH, and the second from John Ashmeade, Senior Assistant Counsel at YNHH. *See* ECF No. 130, Exs. 13-14. Ashmeade's affidavit includes timesheets supporting all of the legal fees and costs for which YNHH is requesting restitution. *See id.*, Ex. 14. Lee's affidavit deals with all of the other expenses for which YNHH seeks restitution, including the expenses for administrative time responding to the contamination, and likewise includes timesheets and other supporting documentation relating to those expenses. *See id.*, Ex. 13. The Court has reviewed these affidavits and their exhibits and finds that they provide sufficient support for YNHH's declared losses.

CONCLUSION

For the reasons discussed above, the Court will impose restitution in the full amount requested by YNHH: \$825,363.15. An appropriate order will follow.

Dated: Brooklyn, New York
March 13, 2018

/s/_____
I. Leo Glasser